# Chem-Bio News

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- 3. EMERGENT BIOSOLUTIONS RECEIVES FDA APPROVAL FOR BIOTHRAX
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- **4. MAN-MADE SARS VIRUS SPREADS FEAR:** "US scientists have created a synthetic SARS-like virus, sparking fears about the increasing ease with which bioweapons could be created in test tubes."

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1. US ARMY CHEMICAL MATERIALS AGENCY -PUBLIC LAWS IMPACTING THE U.S.

ARMY CHEMICAL WEAPONS STORAGE AND DISPOSAL PROGRAM: "This is a synopsis of the main public laws pertaining to CMA, organized by subject matter and updated annually to reflect changes in public law."

# **CB** Daily Report

# Chem-Bio News

#### **OBAMA NAMES CLIMATE CHANGE EXPERTS TO POSTS**

By Stephen Dinan The Washington Times December 20, 2008

"He [Obama] tapped John Holdren, a physicist from Harvard's Kennedy School of Government, to be his science adviser; named Harold Varmus and Eric Lander to round out the President's Council of Advisers on Science and Technology; and said he will nominate Jane Lubchenco to be administrator of the National Oceanic and Atmospheric Administration."

"Mr. Holdren has weighed in on other issues, including calling on the U.S. to issue a "no first use" policy for nuclear weapons and to take nuclear retaliation off the table as a response to chemical or biological attacks."

The full article can be found at: http://www.washingtontimes.com/news/2008/dec/20/obama-names-climate-change-experts-posts/

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#### HOBBYISTS ARE TRYING GENETIC ENGINEERING AT HOME

By Marcus Wohlsen PhysOrg.com December 26, 2008

"....., a computer programmer by day, conducts an experiment in the dining room of her San Francisco apartment on Thursday, Dec. 18, 2008. Patterson is among a new breed of techno rebels who want to put genetic engineering tools in the hands of anyone with a smart idea. Using homemade lab equipment and the wealth of scientific knowledge available online, these hobbyists are trying to create new life forms through genetic engineering - a field long dominated by Ph.D.s toiling in university and corporate laboratories."

"But critics of the movement worry that these amateurs could one day unleash an environmental or medical disaster. Defenders say the future Bill Gates of biotech could be developing a cure for cancer in the garage.

Many of these amateurs may have studied biology in college but have no advanced degrees and are not earning a living in the biotechnology field. Some proudly call themselves "biohackers" - innovators who push technological boundaries and put the spread of knowledge before profits.

In Cambridge, Mass., a group called DIYbio is setting up a community lab where the public could use chemicals and lab equipment, including a used freezer, scored for free off Craigslist, that drops to 80 degrees below zero, the temperature needed to keep many kinds of bacteria alive."

The full article can be found at: http://www.physorg.com/news149485258.html

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# EMERGENT BIOSOLUTIONS RECEIVES FDA APPROVAL FOR BIOTHRAX SUPPLEMENTAL BIOLOGICS LICENSE APPLICATION - REDUCED DOSAGE AND INTRAMUSCULAR ADMINISTRATION APPROVED

Emergent Biosolutions Press Release December 19, 2008

"Emergent BioSolutions Inc. (NYSE:EBS) announced today that the U.S. Food and Drug Administration (FDA) has approved Emergent's supplemental Biologics License Application (sBLA) for Anthrax Vaccine Adsorbed (BioThrax(R)), the only FDA-licensed vaccine to prevent disease caused by Bacillus anthracis. The supplement provides for a change in the route of administration and a reduction in the total number of vaccinations. The new schedule for BioThrax is five intramuscular (IM) doses at 0, 1, 6, 12 and 18 months, compared with the former schedule of six subcutaneous (SC) doses at 0, 2 weeks and 1, 6, 12, 18 months.

The sBLA was based on results from a planned interim analysis of data from a large multicenter study initiated by CDC in 2002. This study is designed to evaluate whether as few as three doses of BioThrax administered over six months, with booster doses up to three years apart, will confer an adequate immune response. CDC will complete further data analysis in 2009, and Emergent may submit a new sBLA to allow for further reduction in the number of required doses if supported by the data."

The full article can be found at: http://www.emergentbiosolutions.com/NewsReleases.aspx? ReleaseID=1238013

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#### MAN-MADE SARS VIRUS SPREADS FEAR

By Nyssa Skilton The Canberra Times December 24, 2008

- "US scientists have created a synthetic SARS-like virus, sparking fears about the increasing ease with which bioweapons could be created in test tubes."
- "The director of Australia's National Centre for Biosecurity, Professor Ian Ramshaw, said the move signalled a new wave of problems in biosecurity.
- "They were allowed to create a new virus without absolutely knowing how dangerous it might be," Professor Ramshaw said.
- "It's getting very, very easy now to make these things in the test tube."
- "United States researchers from the Vanderbilt Medical Centre and the University of North Carolina at Chapel Hill generated the synthetic bat virus to try to understand how it might have jumped from bats to humans. They have reported their findings and descriptions of the virus in the Proceedings of the National Academy of Sciences.
- Professor Ramshaw said people did not need lot of expertise to produce a virus once they knew its genetic sequence.
- All that was required was to send the sequence to a "designer DNA firm", which would create the sequence. "There's no regulation of these designer DNA firms around the world

that prevents them from making these sequences that I will send off in an email and it will be sent back in the post," he said."

The full article can be found at: http://www.canberratimes.com.au/news/local/news/general/manmade-sars-virus-spreads-fear/1394539.aspx?storypage=1

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# Chem-Demil News

US ARMY CHEMICAL MATERIALS AGENCY -PUBLIC LAWS IMPACTING THE U.S. ARMY CHEMICAL WEAPONS STORAGE AND DISPOSAL PROGRAM US Army Chemical Materials Agency Fact Sheet December 3, 2008

"Congressional oversight and public laws guide the U.S. Army Chemical Materials Agency (CMA) in its mission to protect and safely eliminate the nation's aging chemical weapons, while CMA works toward the effective recovery, treatment and elimination of chemical warfare material as well as enhancing national security.

This is a synopsis of the main public laws pertaining to CMA, organized by subject matter and updated annually to reflect changes in public law. To obtain copies of the specific federal laws referenced, please contact CMA's Public Affairs Office or a local outreach office.

Chemical Weapons Disposal Program Mission

In 1985, Congress directed the secretary of defense to oversee destruction of the U.S. chemical weapons stockpile. In doing so, the secretary is to ensure maximum protection of the environment and the general public, as well as workers involved in chemical weapons destruction. (Public Law 99-145, 1985.)

Congress designated the Army as the military organization responsible for safely destroying the chemical agent and weapons stockpile located in the United States. (Public Law 99-145, 1985.) The Army's program was created to manage the daily operations of chemical agent and weapons disposal and can be directed by either a civilian or general officer. (Public Law 99-145, 1985; Public Law 100-456, 1988; and Public Law 104-106, 1996.)

The chemical weapons stockpile must be destroyed by April 29, 2007, in accordance with the Chemical Weapons Convention, an international treaty. (Senate Resolution 75, 1997.)

In 1992, Congress directed the secretary of the Army to provide a report on the Army's plan for destroying all chemical warfare materiel that is not part of the stockpile. These chemical weapons are known as "non-stockpile chemical materiel" and include buried chemical weapons, binary chemical weapons, former chemical warfare production facilities, chemical weapons recovered from ranges and miscellaneous chemical warfare materiel. (Public Law

102-484, 1992.)

# Stockpile Stability

In 1992, Congress directed the Army to prepare and submit a report on the physical and chemical integrity of the chemical weapons stored within the (then) eight chemical weapons storage sites in the continental United States. (Public Law 102-484, 1992.)

# The Disposal Process

All facilities used in the destruction of chemical weapons must be designed solely for that purpose. (Multiple years, most recent Public Law 106-65, 1999.)

When disposing of chemical weapons, the Army must meet or exceed applicable federal and state environmental and safety requirements. (Public Law 99-145, 1985.)

Facilities constructed to dispose of stockpiled chemical weapons and related materiel also can be used to destroy non-stockpile chemical materiel if the state in which a destruction facility is located issues the appropriate permit(s) for the destruction of such items at that facility. However, the Anniston Chemical Agent Disposal Facility cannot be used for the disposal of any non-stockpile materiel that is not already stored at Anniston Army Depot. (Public Law 106-65, 1999 and Public Law 106-398, 2000.)

# **Evaluation of Alternative Technologies**

In 1992, Congress directed the Army and the National Research Council to report on potential alternatives to the baseline incineration technology. Congress directed that an alternative technology could be pursued at low-volume chemical weapons sites if the secretary of the Army determined that the technology could meet the stockpile elimination deadline and was significantly safer and more cost-effective than baseline incineration. Provided that these conditions were met, Congress also permitted the use of alternative technologies at other stockpile sites if the secretary of the Army notified Congress of the intent to do so. (Public Law 102-484, 1992.)

In 1996, Congress directed the secretary of defense to conduct a pilot program to identify and demonstrate not less than two alternatives to the baseline incineration technology with possible application at Pueblo, Colo., and Richmond, Ky. This program has come to be known as the Assembled Chemical Weapons Alternatives (ACWA). The pilot program was to be carried out by a manager who has not been in direct or immediate control of the current incineration technology. (Public Law 104-208, 1996.)

As with incineration, all alternative technologies identified under ACWA must meet or exceed applicable federal and state environmental and safety requirements. An annual report must be sent to congressional defense committees detailing the pilot program's activities along with a final report detailing the effectiveness of each alternative technology identified and demonstrated. (Public Law 104-208, 1996.)

As a result of the legislation creating ACWA, the contracts for technology-specific construction at Pueblo, Colo., and Richmond, Ky., were put on hold until 180 days after a final report on the Alternative Technologies Pilot Program was issued. (Public Law 104-208, 1996.)

In 1999, Congress ordered that the chemical disposal facility at Richmond, Ky., could not be constructed until after the Department of Public Laws Impacting the U.S. Army Chemical Weapons Storage and Disposal Program Defense had demonstrated six alternatives to baseline incineration for the disposal of chemical weapons. (Public Law 106-52, 1999.)

In 2000, Congress ordered the Department of Defense to consider only those technologies demonstrated before May 1, 2000, for destruction of chemical weapons at Pueblo Chemical Depot. (Public Law 106- 398, 2000.)

### Transportation of Chemical Weapons

In 1991, Congress ordered the prohibition of studies of the feasibility of removing or transporting the chemical weapons stockpile from any of the (then) eight storage sites in the continental United States. (Public Law 102-172, 1991.) This prohibition has been repeated in follow-on public laws.

Chemical weapons that are not part of the chemical weapons stockpile cannot be transported across state lines. (Public Law 103-337, 1994.)

If a chemical weapon is discovered that is not already part of the stockpile (i.e., non-stockpile materiel), the secretary of defense may transport it to the nearest chemical weapons stockpile storage facility with the necessary permits for receiving and storing such items. (Public Law 103-337, 1994.)

### Site/Facility Closure

In 1992, Congress passed a law prohibiting preparation of studies on the potential future uses of the nine chemical disposal facilities other than for the destruction of stockpile chemical munitions. (Public Law 102-396, 1992 and Public Law 103-335, 1994.)

Upon completing its mission, facilities must be cleaned and disposed of in accordance with mutual agreements between the secretary of the Army and the governor of the state in which the facility is located, as well as in accordance with all federal, state and local laws and regulations. (Multiple years, most recent Public Law 106-65, 1999.)

The Defense Base Realignment and Closure Act would also control part of the consideration for disposal of facilities and storage sites. (Public Law 101-510, 1990.)

# **Emergency Preparedness**

In 1986, Congress established emergency preparedness guidelines for the chemical disposal program. According to Congress, the secretary of defense may make grants to state and local governments (either directly or through the Federal Emergency Management Agency) to assist local governments in carrying out functions relating to emergency preparedness and response in connection with the disposal of chemical agents and munitions. (Public Law 99-145, 1985 and Public Law 101-510, 1990.)

The Federal Emergency Management Agency director, in coordination with the Secretary of the Army, shall help state and local governments develop their individual emergency response systems to deal with emergency situations resulting from the storage and destruction of chemical weapons. (Public Law 105-261, 1998.)

### **Public Participation**

The secretary of the Army will establish a citizens' commission for each state that stores 5 percent or less of the total U.S. stockpile of chemical weapons (Richmond, Ky.; Edgewood, Md.; and Newport, Ind.) and upon a request from the governor of a state where a chemical weapons storage site is located (Anniston, Ala.; Hermiston, Ore.; Tooele, Utah; Pueblo, Colo.; and Pine Bluff Ark.). Citizens' Advisory Commissions were established at each of the stockpile states. (Public Law 102-484, 1992.)

Each commission will be composed of nine members. The governor of each state where a commission is established will appoint seven citizens who live in the affected areas of the state to serve as members of the commission. The other two members will be representatives of state government, who have direct responsibilities related to the chemical disposal program. (Public Law 102-484, 1992.)

The Citizens' Advisory Commissions must meet at least twice a year. (Public Law 102-484, 1992.) Public Laws Impacting the U.S. Army Chemical Weapons Storage and Disposal Program (continued) An Army representative will attend each commission meeting to receive citizen and state concerns regarding the chemical disposal program. (Public Law 102-484, 1992.)

# Reports to Congress

Reports are made regularly to Congress regarding the Army's chemical disposal program. Annually, the secretary of defense must issue a report to Congress that details the program's activities. The report includes information about each chemical weapons stockpile site, an accounting of all funds expended by the program and an assessment of the stockpiles' current safety and integrity. (Public Law 99-145, 1985.) Quarterly, the office of the secretary of defense must issue a report that details the Army's progress in maintaining the program's cost and schedule estimates. (Public Law 107-117, 2002.)

Congress periodically requires additional reports, including reports analyzing the use of alternative technologies, examining impact aid, making assessments of the chemical disposal program, identifying possible measures that can be taken to reduce the cost of the program and evaluating issues concerning closure and reutilization of facilities.

#### Conclusion

Congressional oversight and the public laws guide CMA in safely and securely storing and disposing of the chemical agent munitions stockpile while protecting workers, public and the environment.

In addition to public laws, federal environmental laws also regulate chemical weapons disposal. To learn about those environmental laws, please obtain a copy of the CMA fact sheet "Federal Environmental Laws Governing Chemical Agent Storage and Disposal."

The full article can be found at: http://www.cma.army.mil/fndocumentviewer.aspx?docid=003671065

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